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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/940,550   | 08/27/2001  | Luke Mankin          | 16313-0055          | 4978             |
| 29052  | 7590        | 12/09/2003           | EXAMINER            |                  |
| SUTHERLAND ASBILL & BRENNAN LLP<br>999 PEACHTREE STREET, N.E.<br>ATLANTA, GA 30309 |             |                      |                     | FOX, DAVID T     |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             | 1638                 |                     |                  |

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/940,550

Applicant(s)

MANKIN ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 11 September 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 10-20, 26, 28, 29 and 39-60 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9, 21-25, 27 and 30-38 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 091103.      6) Other:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' amendments of 11 September 2003 have obviated the claim objections, the art rejections, and the enablement rejection of claims 32-34.

Claims 1-9, 21-25, 27 and 30-38 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last Office action on pages 3-5.

Claims 1-9, 21-25, 27, 30-31 and 35-38 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to polynucleotides comprising a plant somatic tissue-specific promoter ligated to a gene encoding a phi C31 recombinase for controlled excision of desired trait polynucleotides in plants, does not reasonably provide enablement for claims broadly drawn to any irreversible recombinase system or animal transformation constructs or systems. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last Office action on pages 6-8 for claims 1-9, 21-25, 27 and 30-38.

The claims are deemed free of the prior art, given the failure of the prior art to teach or suggest plant transformation with a construct comprising a gene encoding an

irreversible recombinase and a heterologous trait gene to be removed by said recombinase when flanked by corresponding recombinase recognition sites.

No claim is allowed.

Applicants' arguments filed 11 September 2003 have been fully considered but they are not persuasive.

Applicants urge that the written description rejection is improper, given the availability of tissue-specific promoters functional in plants and animals. The Examiner maintains that most of the tissue-specific promoters listed in the specification are seed-specific or fruit-specific, rather than "somatic tissue-preferred" as newly claimed. The specification does not provide any information regarding animal tissue-specific promoters. See MPEP 2163 cited previously, which teaches that a correlation between structure (i.e. gene sequence) and function (i.e. somatic tissue-preferred gene expression) must be demonstrated in order to provide an adequate written description. Applicants have not provided such information for the broadly claimed genus.

Furthermore, Applicants have not reduced to practice any plants transformed with a multitude of somatic tissue-preferred promoters and a multitude of irreversible recombinase-encoding genes, including the phi C31 recombinase. The specification merely provides diagrams of genetic constructs comprising reproductive tissue-preferred promoters and the phi C31 recombinase gene, and prophetic examples of plant transformation therewith. See MPEP 2163 which states that an invention may not be adequately described solely based upon a method of making it.

Applicants urge that the enablement rejection is improper, given the multiple working examples disclosed in the specification, the assertion that only routine experimentation would have been required, the ability of other workers to utilize the phi C31 recombinase system to transform plants and animals, the ability of other workers to utilize other irreversible recombinase systems to transform animal cells, and the ability of other workers to transform animal cells with somatic tissue-preferred promoters, as demonstrated by references appended to the amendment of 11 September 2003.

The Examiner disagrees that multiple working examples of the claimed invention, namely plant transformation with any irreversible recombinase gene and any somatic tissue-preferred promoter, have been provided. In fact, no working examples of these concepts have been provided, as stated above.

Regarding Applicants' assertions that the amount of experimentation is merely routine, the Examiner maintains that he has cited a publication and utilized scientific reasoning to refute these assertions, and that Applicants' own cited publications support his position. For example, Groth et al report that other recombinase systems using other viral integrase genes require host cofactors and produce low levels of transformation (see, e.g., page 6000, column 2, first full paragraph).

The Examiner maintains that no other irreversible recombinase system besides the exemplified phi C31 recombinase has been demonstrated to work in plants. Regarding the use of other irreversible recombinase systems in animals, the Examiner maintains that the art cited by Applicants relies upon specialized techniques and starting materials not disclosed in the instant specification. Young et al teach that the adeno-

associated viral Rep protein requires additional sequences in human chromosome 19 (see, e.g., page 3957, second full paragraph). Lamartina et al teach that this region is a hotspot of human chromosome 19 (see, e.g., page 7671, Abstract). Dutheil et al teach that a closely linked TNNT1 muscle-specific gene on chromosome 19 is required (see, e.g., page 4862, Abstract and page 4866, column 2, second paragraph). The instant specification provides no guidance for any of these concepts.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a “mere germ of an idea does not constitute [an] enabling disclosure”, and that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

Similarly, the references cited to support the use of animal somatic tissue-preferred promoters all require additional starting materials and processes not taught by the instant specification. Guillot et al (page 77, column 2, middle paragraph) and Evans et al (page 67, column 2, bottom paragraph) teach that an embryonic stem cell line lacking a functional X-lined Hprt gene is required in their process. Swoap et al teach that an intramuscular injection technique is required, as are overexpression plasmids with mutant NFAT genes (see, e.g., page C916, column 2, first full paragraph and penultimate paragraph). See *Genentech* cited above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 1, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

